EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Preparation and Review of Standard Operating Procedures (SOPs)

SOP ADM-02-01

Date Revised: 02-12-03

Prepared By: _____Date: ___/___/___

Print Name:_____

Reviewed By: _____ Date: ___/___/___

Print Name:_____
Technical Staff

_____ Date: ___/___/___

Print Name:_____
QA Officer

_____ Date: ___/___/___

Print Name:_____
Laboratory Director

Date Issued: ___/___/___

Withdrawn By: _____ Date: ___/___/___

Controlled Copy No.: _____

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1.0 SCOPE AND APPLICATION:

1.1 The purpose of this procedure is to provide guidance in the preparation of Standard Operating Procedures (SOPs) for the Office of Pesticide Programs' Microbiology Laboratory located at the Environmental Science Center, Fort Meade, Maryland.

1.2 This procedure applies to the development and oversight of all SOPs used by the lab staff, the quality assurance unit, and the laboratory director.

2.0 DEFINITIONS:

2.1 Standard Operating Procedure (SOP): A document which gives a step-by-step description of how a specific operation, method or procedure is performed.

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS: None

5.0 INTERFERENCES: None

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS:

7.1 Hard and/or electronic copies of the SOPs and addenda prepared using the Agency's acceptable software in use at the time of their preparation.

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE: Not applicable

10.0 PROCEDURE AND ANALYSIS:

10.1 Summary. Each SOP shall be written in the standard laboratory format. The following procedure describes the organization and format of SOPs, their review and approval, distribution, revision and storage.

10.2 SOP Identification. SOPs are organized into groups according to subject area. Each SOP shall be assigned a unique number. An example of the identification format is presented below:

ADM-01-01 (Group ID - SOP No. - Revision No.)

The first two to three alphabetical characters identify the grouping. The middle two-three digit number is the assigned SOP number in that group. The last two-digit number is the revision number for that SOP. Revision "00" is the original version of the SOPs.

The following group letters shall be used to identify SOP categories:

ADM - Administrative
COC - Chain-of-Custody
QC - Quality Control
EQ - Equipment Calibration and Maintenance
MB - Microbiology
QA - Quality Assurance

10.3 Title Page. Every SOP shall have a title page (see 16.0) which shall identify it as an SOP for the OPP Microbiology Laboratory. The title page contains the title of the SOP, the SOP identification number, and the date revised. Except for the QA-series of SOPs, the title page also identifies who prepared and reviewed the SOP, and approval signatures for the QA Officer, and the Laboratory Director.

The QA group SOP title page contains the dates of review/approval and signatures of the author (Quality Assurance Officer), the Laboratory Director, and the OPP Quality Assurance Manager.

10.4 Page Identification. The top right corner of each page, following the cover page, shall contain the following information:

SOP No. __-__-__
Date Revised: __-__-__
Page __ of __

10.5 All SOPs shall contain a Table of Contents (always considered as page 1) and the following sections and format:

10.5.1 1.0 SCOPE AND APPLICATION: This section describes the reason for writing the SOP, with its intended use and effect.

10.5.2 2.0 DEFINITIONS: This section lists definitions of terms relevant to this SOP, or with which the reader may be unfamiliar. When there is no need to define terms, the format shall read:

2. 0 DEFINITIONS: None

10.5.3 3.0 HEALTH AND SAFETY: This section will highlight any unique health or safety issues pertaining to the specific SOP. All SOPs will refer to the most recent version of SOP MB-01, Lab Biosafety, for comprehensive health and safety procedures and policy. When there is no need to define health and safety practices, the format shall read:

3.0 HEALTH AND SAFETY: Not applicable.

10.5.4 4.0 CAUTIONS: This section will identify any known critical control points or technique sensitive procedures (e.g., inoculum production, timing of transfers of carriers, etc.) found in the protocol. If there are no cautions identified, the format shall read:

4.0 CAUTIONS: None

10.5.5 5.0 INTERFERENCES: This section discusses any potential or known problems that may be encountered during

the performance of a method or procedure that may complicate interpretation or validity of results (e.g., incomplete neutralization, contamination of pre-sterilized supplies, etc.). If there are no known interferences, the format shall read as follows:

5.0 INTERFERENCES: None

10.5.6 6.0 PERSONNEL QUALIFICATIONS: This section identifies the education or training that is required to carry out the procedures covered by the SOP. Modify standard text as necessary for the specific SOP. The standard text is:

"Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee."

10.5.7 7.0 SPECIAL APPARATUS AND MATERIALS: Lists special or unique instruments and supplies needed to perform the method. If there are no special apparatus or materials specified, the format shall read:

7.0 SPECIAL APPARATUS AND MATERIALS: None

10.5.8 8.0 INSTRUMENT OR METHOD CALIBRATION: Describes the method and frequency of calibrating an instrument or piece of equipment. If this is not applicable to the SOP, the format shall read:

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

10.5.9 9.0 SAMPLE HANDLING AND STORAGE: Describes the conditions of preservation and storage required to maintain the integrity of the sample. Holding times shall be specified. If this is not applicable to the SOP,

then the format shall read:

9.0 SAMPLE HANDLING AND STORAGE: Not applicable

10.5.10 10.0 PROCEDURE AND ANALYSIS: Provides a step-by-step description of the operation.

10.5.11 11.0 DATA ANALYSIS/CALCULATIONS: Provides instructions for data reduction and equations and definitions of constants necessary to produce the results of the method. If there are no analyses or calculations, the format shall read:

11.0 DATA ANALYSIS/CALCULATIONS: None

10.5.12 12.0 DATA MANAGEMENT/RECORDS MANAGEMENT: This section describes the procedures that will be used to meet Agency, OPP, and GLP data management/records management requirements. Insert standard text, modified as necessary, to fit the specific SOP. The standard text is:

"Data will be recorded promptly, legibly, and in indelible ink on the appropriate forms. Completed forms are archived in notebooks kept in locked file cabinets in the file room D217. Only authorized personnel have access to the locked files. Archived data is subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives."

10.5.13 13.0 QUALITY CONTROL: This section describes the procedures used to meet GLPs. Insert standard text, modified as necessary to fit the specific SOP. The standard text is:

"The OPP Microbiology Laboratory conforms to 40CFR Part 160, Good Laboratory Practices. Appropriate quality control measures are integrated into each

SOP. For quality control purposes, the required information is documented on the appropriate forms. (See attachments_____)"

10.5.14 14.0 NONCONFORMANCE AND CORRECTIVE ACTION: This section describes the communication and documentation required when a problem arises. It also describes a means of correcting the problem to prevent recurrence. At a minimum, the following statement is included:

"Any deviations from the standard protocol or any problems which occur during analysis must be documented in the raw data and on the GLP statement and corrective action applied if warranted."

10.5.15 15.0 REFERENCES: This section lists any document used as a source for writing the SOP such as standard methods, QA Manual, publications, and instrument manuals. References shall be listed alphabetically. When no references were used, the format shall read:

15.0 REFERENCES: None

10.5.16 16.0 FORMS AND DATA SHEETS: This section lists the forms and data sheets referenced in the SOP. If no forms or data sheets are referenced, the format shall read:

16.0 FORMS AND DATA SHEETS: None

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Documentation used for initiating, revising, issuing, and withdrawal of an SOP will be recorded on the SOP title page. SOPs will be written and stored using the Agency's standard word processing software.

12.2 The QA Officer is responsible for issuing controlled copies of approved SOPs to each laboratory and to appropriate personnel. The date of issuance is recorded on the SOP title page. (see 16.1).

12.3 Following completion of the SOP revision process, the QA Officer is responsible for collecting the previous version of all controlled copy SOPs . Controlled copy number 0 will be retained as an archived copy. All other copies will be destroyed.

12.4 The QAU maintains archived SOPs in a locked file cabinet located in D217. Only authorized personnel have access to the locked files. Archived files are subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 All SOPs prepared by the laboratory staff must be reviewed by the Team Leader and the QA Officer. After review and comment by the Team Leader and the QAO, the SOP is routed to the Laboratory Director for approval. A copy of the SOP is attached to the OPP Quality Assurance Management Plan which is sent to the OPP QA Manager for approval. Each reviewer is responsible for ensuring that the procedures are adequate and accurate based on his/her area of expertise.

13.2 The SOPs are reviewed and revised at least every three years. If during the use of an approved SOP, a major modification is required, the SOP will revised at that time. If there is a need for a minor modification or amendment, an addendum to the SOP will be prepared. The team leader is responsible, in consultation with the QA officer, for determining whether the SOP changes are major or minor.

13.3 Any member of the laboratory team can request a modification or amendment to an SOP. The changes should be discussed with the laboratory team leader prior to preparing an addendum. The addendum or new SOP shall circulated for review and approval. At the time of the three year review cycle, all amendments or modifications made via the addenda process will be incorporated into the SOPs.

13.4 The withdrawal of an SOP from use is documented on the SOP title page

on the controlled copy 0. Copy 0 is archived. All other controlled copies are destroyed.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Any deviations from the SOP or standard protocol or any problems which occur during analysis must be documented in the raw data and on the GLP statement. Corrective action will be taken if warranted.

15.0 REFERENCES:

15.1 US EPA Good Laboratory Practices, Title 40 Code of Federal Regulations (CFR) Part 160.

15.2 US EPA Office of Research and Development. November 1995. Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents, EPA QA-G6. EPA/600/R-96/027.

16.0 FORMS AND DATA SHEETS:

16.1 SOP Review Summary/Cover Sheet for SOPs except QA SOPs

16.2 SOP Review Summary/Cover Sheet for QA SOPs

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Name of SOP Here

SOP Number:

Date Revised: MM-DD-YY

Prepared By: _____Date: ___/___/___

Print Name:_____

Reviewed By: _____ Date: ___/___/___

Print Name:_____
Technical Staff

_____ Date: ___/___/___

Print Name:_____
QA Officer

_____ Date: ___/___/___

Print Name:_____
Laboratory Director

Date Issued: ___/___/___

Withdrawn By: _____ Date: ___/___/___

Controlled Copy No.: _____

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
[Quality Assurance Operations]

SOP QA-01-00

Date Revised: MM-DD-YY

Prepared By: _____Date:___/___/___

Print Name:_____
Quality Assurance Officer

Reviewed By: _____ Date: ___/___/___

Print Name:_____
Laboratory Director

_____ Date: ___/___/___

Print Name:_____
OPP Quality Assurance Manager

Date Issued: ___/___/___

Withdrawn By: _____ Date: ___/___/___

Controlled Copy No.: _____